DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention

February 9, 2009

Dear Colleague,

This letter is to provide health care providers with information about a recall of Azithromycin 500mg tablets manufactured by Greenstone. Azithromycin is the recommended treatment for chlamydial infections.

Greenstone issued a voluntary retail-level drug recall on December 29, 2008 for one lot (NDC 59762-3070-2 Lot 6HP033A) of Azithromycin 500mg tablets - 30 count bottles because the lot may not meet dissolution specifications on stability (see attachment). The affected lot was shipped between August 2006 and August 2007 and has an expiration date of May 2009.

CDC has been in contact with Pfizer/Greenstone and the U.S. Food and Drug Administration (FDA) to gather information regarding the extent of the situation and the impact on the efficacy of the recalled medication. Based on the information we have received, we recommend that STD programs do the following:

1. Adhere to the instructions in the Drug Recall letter:
    a. Check your inventory for the affected lot.
    b. Discontinue the distribution of the affected lot.
    c. Work with your site procurement organization to coordinate return of the affected lot to Stericycle, Inc.

2. Review your mechanism for monitoring lot numbers and expiration dates for medications received and distributed by your STD program.

3. Health care providers are encouraged to retest patients with chlamydial infections according to the 2006 STD Treatment Guidelines.

4. If a patient was treated for a chlamydial infection with the affected lot and has a treatment failure, providers should 1) retreat the patient using another alternative (either by using a different lot of the same product or another comparable medication) and 2) report the treatment failure to the FDA MedWatch.

Please circulate this guidance to other colleagues who may have received the recalled product. Healthcare professionals with medical inquiries on azithromycin can contact Pfizer Medical Information at (800) 438-1985. For additional questions regarding the recall, contact Neisa M. Alonso, Consumer Safety Officer, Recall & Emergency Coordinator, U.S. Food and Drug Administration at (787) 474-9501 or Neisa.Alonso@FDA.HHS.GOV.

Sincerely,

/John M. Douglas, Jr./

John M. Douglas Jr., MD
Director
Division of STD Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

William C. Kennally III
President

GREENSTONE
LLC

100 Route 206 North
Peapack, NJ 07977

URGENT: DRUG RECALL

December 29, 2008

Azithromycin 500 mg Tablets

NDC	Lot	Expiration	Strength	Configuration/Count
59762-3070-2	6HP033A	May 2009	500 mg tablet	30 count bottles

Dear Customer:

Greenstone LLC is voluntarily recalling the above referenced lot of **Azithromycin 500 mg tablets**. Greenstone LLC voluntarily initiated this recall when it was determined that the above mentioned lot may not meet dissolution specifications on stability. Please note that when using this product as directed, the probability of serious adverse health consequences is remote.

Please note that the NDC number stated on the bottle is 59762-3070-2. The NDC number currently listed with the FDA is 59762-3070-1. Greenstone has decided with FDA to revise and list the NDC number 59762-3070-2 as stated on the bottle. **This recall only involves lot 6HP033A in the package configuration of 30 count bottles; it does not affect the blister pack configuration.**

FEDERAL REGULATIONS REQUIRE THAT YOU RESPOND TO THIS RECALL, EVEN IF YOU DO NOT HAVE THE RECALLED PRODUCT. **TO RESPOND, COMPLETE THE REQUESTED INFORMATION ON THE ENCLOSED POSTAGE-PAID, BUSINESS REPLY CARD AND RETURN IT TO US WITHIN FIVE (5) BUSINESS DAYS.**

The recall of **Azithromycin tablets** is being conducted to the **retail level**.

Our records indicate that you may have received shipment of the affected lot between **August 2006** and **August 2007**. Please check your stock immediately against the table above. If you have any of the affected product in your inventory, please stop distribution and promptly return to **Stericycle Inc.; 2670 Executive Drive Suite A; Indianapolis, IN 46241; Attn: Greenstone LLC – Azithromycin tablets** using the enclosed pre-paid UPS label. If you require additional shipping labels or have questions regarding the return procedure, please contact Stericycle Inc. at 1-800-805-3093.

If you have further distributed this lot to wholesale or retail level accounts, please conduct a sub-recall and communicate this recall information to those accounts immediately. Please request that they immediately cease distribution of the affected lot and promptly return the product directly to the above address (your accounts do not need to fill out a business reply card; however, if they have inventory of the affected product, they can contact Stericycle Inc. at 1-800-805-3093 to obtain pre-paid shipping labels for product return). Further authorization is not required for product return. Reimbursement for the returned product will be made by credit memorandum. If you have any questions regarding the reimbursement, please contact your Greenstone Customer Service Representative at 1-800-447-3360.

This recall is being conducted with the knowledge of the Food and Drug Administration. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience you may have been caused by this action. If you have any questions regarding the product, please contact Pfizer (Greenstone) Medical Information at 1-800-438-1985.

Sincerely,

WCKennally

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